

**HASQARD Focus Group**  
Meeting Minutes  
November 6, 2018

The meeting was called to order by Jonathan Sanwald, HASQARD Focus Group Chair at 2:05 PM on November 6, 2018 in Conference Room 308 at 2420 Stevens Center Place.

Those attending were: Jonathan Sanwald, HASQARD Focus Group Chair (Mission Support Alliance (MSA)), Cliff Watkins - Focus Group Secretary (Corporate Allocation Services, U.S. Department of Energy – Richland Operations Office (RL) Support Contractor), Ryan Beach (U.S. Department of Energy – Office of River Protection (ORP), Glen Clark (Washington River Protection Solutions (WRPS)), Jim Douglas (CH2MHILL Plateau Remediation Company (CHPRC)), Fred Dunhour (ORP), Anthony Nagel (CHPRC ), Geoff Schramm (WRPS), Tricia Wood (Wastren Advantage Inc. Wastren Hanford Laboratory (WHL)).

- I. Due to the change of venue for this meeting, the Chair requested review and approval of the meeting minutes from the HASQARD Focus Group held on September 25, 2018 while waiting for others to find the meeting location. The draft minutes from the meeting were distributed and time was allowed for one final review. Hearing no comments on the draft meeting minutes, the minutes from the September 25, 2018 meeting were approved.
- II. The HASQARD Focus Group has a standing agenda item to discuss the status of activities associated with the DOE Consolidated Audit Program – Accreditation Program (DOECAP-AP) at all HASQARD Focus Group meetings. This month, the following updates were discussed:

Jim Douglas stated that Scot Fitzgerald had attended the assessment conducted at Test America – Richland (TARL) in late September. Jim had not received any specific feedback from Scot on that assessment.

Glen Clark stated that Robert Elkins had represented WRPS at the TARL DOECAP-AP assessment and Robert and Judy McCluskey had represented WRPS at an assessment conducted by the DOECAP-AP at Columbia Basin Analytical Laboratories (CBAL).

Glen said that WRPS has now observed at five separate DOECAP-AP assessments and have seen all three of the DOECAP-AP Accrediting Bodies (ABs) perform these assessments. Glen's impression has been that most of the assessors are very good. The main issue WRPS is having with the process is that they have not received a completed checklist from any of these assessments. The DOECAP-AP will not provide these checklists to DOE Contractors. However, WRPS has requested the laboratories to provide the completed checklists. The completed checklists will be used to allow WRPS

to be satisfied with the way the ABs are documenting that requirements are being met. Once WRPS feels that the ABs are adequately documenting requirements are met, they will be more comfortable that the DOECAP-AP will meet their supplier evaluation needs.

Glen Clark continued by saying that assuming the DOECAP-AP is working, he recommends that the Focus Group continue to phase out HASQARD Volume 4 in favor of the Department of Defense (DoD)/DOE Quality System Manual (QSM). Glen stated that Steve Clark of DOE-HQ has been very willing to work with the Hanford Contractors to ensure the DOECAP-AP is meeting the Contractors' requirements. One Focus Group member asked which AB had conducted the assessment at CBAL and Glen replied that it was the American Association for Laboratory Accreditation (A2LA). Glen said that Robert Elkins had reported that one assessor at the assessment did not use a checklist, only a notepad. Glen said that perhaps this assessor works with only a note pad routinely, but WRPS wants to see a completed checklist to document these assessments. It is Glen's understanding that the DOECAP-AP requires that checklists be completed. The checklist is used to document compliance with each requirement. The completed checklist is what WRPS wants to see from the ABs. Glen stated that a standard observation made at the five assessments WRPS has observed is that the ABs don't understand the need for the HASQARD gap checklist and/or don't schedule time to get it completed. It has often been the case that WRPS personnel have either had to train the AB personnel on the need for/use of the HASQARD checklist or have had to complete it for the AB. Often, WRPS personnel find themselves having to assess the laboratory using the HASQARD gap checklist independent of the assessment being conducted by the AB because that HASQARD checklist is not part of the DOECAP-AP yet (i.e., is not contained in the current revision of the QSM).

Jonathan Sanwald stated that the input just presented by Glen makes it sound like the DOECAP-AP is not being implemented as DOE-HQ advertised it would be.

Jim Douglas added that because the HASQARD gap checklist is not in the QSM yet, Jim had to complete the HASQARD gap checklist at the ALS-Ft. Collins assessment. Jim stated that the AB in charge of that assessment (Perry Johnson Laboratory Accreditation, Inc. (PJLA)), issued findings based on deficiencies Jim found at the laboratory using the HASQARD gap checklist. Glen Clark said that the AB is not supposed to issue findings based on the HASQARD gap checklist until it is in an issued revision of the QSM. Jim Douglas agreed and said that when the observers caucused after the assessment, there were several opinions expressing dissatisfaction with PJLA's performance on the ALS-Ft. Collins assessment.

Glen Clark stated that he agrees that of the DOECAP-AP assessments WRPS has observed, those conducted by PJLA were the weakest. Glen speculated that this weakness was due to the expectation mismatch between the AB and the laboratory. Glen felt this was especially true in the area of IH analyses since the QSM does not address the IH requirements as well as it should.

Jim Douglas added that part of the problem with these assessments is that the planning seems to be inadequate. For the ALS-Ft. Collins assessment, PJLA did not hold a conference call between the assessment team and observers until a week before the assessment began. Jim stated that during the call, he pointed out that the HASQARD gap checklist would be applicable to this assessment. The PJLA personnel were not aware that the HASQARD checklist would be required. As a result, the observers came away feeling like the AB could have been better prepared for this assessment than they were upon arrival.

Glen Clark echoed the concern that planning and communication ahead of the assessment seems to be lacking for the DOECAP-AP assessments conducted to date. Glen gave the example of the assessment Robert Elkins observed that was conducted at the Eurofins laboratory. This assessment was scheduled for only a one-day duration. As a result, all of the assessors involved in the assessment felt they were rushed and did not have enough time to complete their assigned evaluations during the assessment. This opinion was also expressed to Robert by Joe Pardue who has been conducting DOECAP audits for many years and knows the checklist he was assigned extremely well. Glen stated that the fact that Joe did not have enough time clearly demonstrated the AB's lack of understanding of the detail required to complete these assessments properly. This issue was noted in the feedback provided by the observers to Steve Clark.

Jonathan Sanwald asked about the upcoming schedule for DOECAP-AP assessments.

Jim Douglas stated that Test America – St. Louis is scheduled for December. This assessment will be conducted by A2LA.

Jim Douglas said Test America – St. Louis will be the last DOECAP-AP assessment in 2018. In February, the DOECAP-AP will return to GEL in Charleston, SC. The first assessment conducted there in 2018 was a “gap assessment” to bring GEL's accreditation up to the DOECAP-AP requirements. Prior to 2018, GEL was only accredited under the DoD accreditation program. Observing this assessment will allow the Hanford observers to see how the DOECAP-AP ABs conduct follow-up on findings noted in the gap assessment.

Jim Douglas stated that he had heard rumor that Steve Clark is trying to reduce the number of observers on the DOECAP-AP assessments.

Glen Clark stated that six observers are being allowed for the GEL assessment scheduled for February. Glen has not felt pressure from Steve Clark to limit observer participation. Glen stated that the ABs don't like a large number of observers. However, the ABs understand that we need to know that they are meeting our requirements.

Jonathan Sanwald added that Steve Clark needs to allow Hanford observers to ensure the HASQARD gap checklist is getting completed during the DOECAP-AP assessments.

Jim Douglas agreed stating that as long as an observer from Hanford is present at every assessment of a laboratory used by a Hanford contractor, we should be able to ensure the checklist is completed. Glen Clark agreed and added the opinion that each contractor that has a subcontract with the laboratory being assessed should send an observer for this first year of DOECAP-AP assessments. This is because the details of the services provided to each contractor is only known by the personnel from that contractor. For example, Robert Elkins attended the DOECAP-AP assessment at Eurofins to represent WRPS. The Eurofins laboratory analyzes samples for dimethyl mercury under their contract with WRPS. When Robert arrived at the Eurofins assessment, he observed the AB assessing the laboratory for methyl mercury only. Without Robert being present to correct the fact that the AB had not understood the scope of the assessment required by WRPS, the assessment would have been completed on an analytical method not required by WRPS.

Cliff Watkins noted the number of "issues" that seem to be occurring in the early stages of the DOECAP-AP and inquired about the process for providing feedback to Steve Clark when the observers have critical opinions to offer. Jim Douglas stated that the observer process requires an evaluation be provided to DOE-HQ after each assessment observed.

Fred Dunhour asked whether any of the HASQARD Focus Group members are on the QSM Data Quality Workgroup (DQW).

Glen Clark stated that he has been offered the opportunity to participate and has joined the DQW. The DQW is not especially active at this time. They have completed their work on the soon to be issued Revision 5.2 of the QSM and won't get started on Revision 6 for a while.

Fred Dunhour asked if the DQW has an interest in the DOECAP-AP and expressed the opinion that data users should be invited to participate along with laboratory QA/QC experts.

Cliff Watkins asked if the fact that the HASQARD checklist will be included as Appendix E of the QSM, will the DOECAP-AP now include issuance of findings against the HASQARD checklist requirements.

Glen Clark stated that because the HASQARD checklist is included as Appendix E, the ABs will be required to assess laboratories that Hanford contracts against that checklist in addition to the balance of the QSM. Any deficiencies noted would result in a finding. Glen added that he plans to use his seat on the DQW to enhance the DOECAP-AP. One specific issue Glen has observed is that there are QC criteria expressed in the QSM Appendix B tables for which no AB has developed a checklist. Jim Douglas agreed saying that when he was a DOECAP auditor, verifying the requirements of the Appendix B tables were being met was a large part of the effort in the audits. Glen Clark agreed adding that there are important differences between the Appendix B tables and what the ABs may think is routinely acceptable QC. For example, when a continuing calibration verification (CCV) analysis fails the QC acceptance criteria, the Appendix B tables specify that corrective action be performed followed by two consecutive, acceptable CCV analyses. This is a unique requirement associated with the QSM since most analytical laboratories simply require one successful CCV analysis to continue analyzing samples.

Cliff Watkins asked if feedback about the ABs not understanding the importance of assessing the Appendix B tables thoroughly was provided to Steve Clark. Glen Clark stated he is working on how to address this with Steve Clark. Glen is hoping that in 2019, when the DOECAP-AP starts performing full assessments at the laboratories, this will be covered.

Jonathan Sanwald asked if the assessments done to date have just been gap assessments and if the DOECAP-AP only assesses laboratories every other year. Glen Clark replied that yes, the DOECAP-AP schedules assessments by calendar year rather than fiscal year. The laboratories they assessed in 2018 were previously accredited under the DoD portion of the QSM. The assessments the DOECAP-AP performed in 2018 were to assess the additional requirements in the QSM associated with DOE only. In 2019, the DOECAP-AP will conduct full assessments at the laboratories that had their last DoD accreditation assessments in 2017. As it turns out, most of the laboratories used by WRPS will be on the DOECAP-AP 2019 full assessment schedule. Jonathan Sanwald asked if after this year, those same laboratories will be re-assessed every other year. Glen Clark stated that would be the case unless a laboratory added a new method. Based on conversations Glen has had with AB assessors, it seems like they spend a lot of time doing mid-term surveillances at laboratories as they seek to be accredited on newly added methods. The DOECAP-AP accredits laboratories by method. Jim Douglas said that CHPRC doesn't often add methods but often add analytes of interest

to be analyzed by a specific method. Glen Clark stated that because the AB accredits by method, CHPRC should be able to review data associated with the laboratory's performance on the method when they add an analyte. Tricia Wood stated that the ABs will use proficiency sample analysis data to add analytes to methods. The issue is that there are not proficiency testing samples available for many analytes.

Fred Dunhour asked if there has been any feedback from the laboratories regarding the DOECAP-AP. Glen Clark responded that most laboratories like this program a lot. The reason for this is that they were already being accredited to the QSM for DoD. By DOE using an accreditation program that can be accomplished at the same time as their DoD accreditation, they are responding to one less assessment per assessment cycle. The laboratories also enjoy using the fact that they are accredited by both the DoD and DOE as marketing material. Some laboratories that have never had to pay for a DOECAP audit and now have to pay for the DOECAP-AP accreditation are not happy. Glen's response to laboratories that are complaining about the cost of accreditation is that they should do what all businesses do when faced with costs of "regulation" and simply raise the price of their services to the consumer to cover these costs of doing business. Jim Douglas echoed this opinion stating that it's not like the DOECAP-AP is inconsistent between laboratories. All laboratories have to do the same thing. Glen Clark stated the CBAL and ALS-Cincinnati have expressed dissatisfaction that they now have to pay for something they never had to pay for before. Because of these concerns, Steve Clark agreed to conduct a DOECAP only audit at ALS-Cincinnati since they only do about \$50K worth of DOE business annually. In the case of CBAL, Steve Clark was not as sympathetic since they do >\$600K in business from WRPS and much more than that when all DOE Contractors are included. Jim Douglas said that CBAL performs a significant amount of geotechnical testing for CHPRC.

Glen Clark asked if Jim Douglas was aware that the DOECAP-AP AB looked at geotechnical testing at CBAL last week. Jim Douglas said he was not aware of that. Jim said that CHPRC had asked if that would be part of the scope before the assessment began but had received no response from the ABs.

Glen Clark stated the QSM Revision 6 is not expected until January 2021. However, the QSM has a Frequently Asked Questions (FAQ) process that could be used to move HASQARD requirements from Appendix E into the main QSM sections as responses to FAQ are provided by the QSM DQW. Glen plans to pose questions to the DQW using the FAQ process. His questions will cite a requirement from the HASQARD checklist, along with a technical basis for the requirement. This will provide the DQW the basis for inclusion of the requirement in the QSM. The responses to FAQ are compiled by the DQW and included in the applicable sections of QSM when the

document is revised.

III. The status of production of Revision 5 of HASQARD was discussed.

The Chair of the Volume 1 subcommittee was not present at this Focus Group meeting. Glen Clark is supporting the Volume 1 subcommittee and was able to report that the Volume 1 subcommittee is planning to take much of the content of Volume 1 out. The scope section will be revised to explain HASQARD is to address Tri-Party Agreement (TPA) analyses (i.e., those conducted to support decisions related to RCRA and CERCLA regulations) only. The scope and applicability of HASQARD will be redefined to acknowledge the QSM as the document that Hanford uses to define technical and QA/QC requirements for analytical laboratories used to provide data applicable to TPA decisions. Because Volume 4 will also be revised to point to the QSM as a source of requirements, and because most of the Volume 1 requirements are relevant only to analytical laboratories, much of the material in Volume 1 is no longer needed. Only the administrative requirements common to the field sampling practices described in HASQARD Volume 2 and/or the field analysis specifications in HASQARD Volume 3 will be retained in HASQARD Volume 1. The subcommittee has recognized that many of the Volume 1 administrative requirements are either too prescriptive for field sampling or are redundant with sampling procedures maintained by the Contractor's sampling organizations. Because the HASQARD will no longer drive analytical laboratory requirements, most of the QA requirements found in Volume 1 are also not necessary because they are redundant with the Contractor's QA program requirements.

Geoff Schramm added that, in the case of WRPS, they should be clearly articulating that a graded approach is being applied to implementation HASQARD within the sampling programs. For example, HASQARD requires annual assessments of sampling activities. If one sampling program only collects samples once per year, is an assessment required every time they go to the field? The HASQARD provides no clarity on what is required in the assessments being specified in the document.

Anthony Nagel stated that a clear definition of "sampling organization" or "organization" would be beneficial also. The current interpretation is that every project collecting samples is a separate organization. Anthony added that it would seem more reasonable if "organization" meant "company." Anthony agreed that the rest of the proposed reduction in specific requirements in Volume 1 of HASQARD make sense assuming all these requirements are addressed in company QAPs, procedures, sampling plans, etc.

Glen Clark stated that the proposed revision to Volume 1 will need a thorough review by all contractors to ensure that requirements that are deleted are

addressed elsewhere in the company's QA program and/or environment project documentation.

Glen stated that the same issue that WRPS and the 222S Laboratory had in adopting HASQARD Revision 4 will be present if the QSM is specified as the source of all analytical laboratory requirements. Specifically, the fact that the QSM requires 24-hour monitoring of the refrigerated sample storage locations with automated notification if a temperature excursion occurs. Fred Dunhour stated that technology evolves quickly and there may be a less expensive solution to this issue than originally estimated. Tricia Wood agreed that an acceptable solution to the temperature monitoring and notification requirement could be found.

Glen agreed to take the input received at this meeting back to the Volume 1 subcommittee and resume production of Revision 5 of Volume 1.

The Chair of the Volume 2 subcommittee, Geoff Schramm stated that Volume 2 is ready for Focus Group review. Cliff Watkins asked whether he had the most recent version of the Volume 2 revision to distribute. Geoff stated that he believes that the most recent version was sent and agreed to send it again. The strategy for review of Volume 2 was discussed. The Focus Group members present stated that the document should be distributed to the voting members and they should distribute the Volume to those in their company that should review it. Comments will be provided to Geoff and he will present the comment resolutions at the next Focus Group meeting.

Jim Douglas stated that the HASQARD Volume 4 subcommittee has yet to reconvene to discuss the revision to this Volume. Glen Clark recommended simply handing off to the QSM in Volume 4. Jim Douglas stated that at this meeting he is hearing a change of direction from what he understood at the last HASQARD Focus Group meeting. At that meeting, he thought that Revision 5 would not completely hand off to the QSM and we would do that in Revision 6 of HASQARD. Others in the Focus Group recalled Rich Weiss expressing the opinion that we are not ready to hand off to the QSM yet but no one knew the details behind Rich's view. Jim Douglas agreed to get a smaller group together to determine how to reduce Volume 4 to a document that points to the QSM for the source of fixed analytical laboratory technical and quality requirements.

IV. The Chair asked if there was any new business for the Focus Group.

Glen Clark stated that he has become aware of a requirement on the HASQARD gap checklist that he believes is adequately covered by the QSM and proposes that he contact the QSM DQW and suggest that the requirements be removed from the Appendix E HASQARD gap checklist before Revision 5.2 of the QSM is issued. The specific requirement from the HASQARD gap



checklist is:

“Over-range samples are diluted or otherwise re-analyzed within the calibration range of the measurement system or, when necessary, reported using defined qualifiers to denote increased quantitative uncertainty.”

The QSM covers this same requirement as follows:

Module 4, Section 1.7.1.1

“When sample response exceeds the calibration range, the laboratory shall dilute and reanalyze the sample (when sufficient sample volume and holding time permit) to bring results within the calibration range. For metals analysis, the laboratory may report a sample result with a response above the calibration range if the laboratory analyzes and passes (within 10% of the true value) a high level check standard that exceeds the sample concentration but is within the linear dynamic range (provided the high level check standard is analyzed in the same manner as the sample and within the same...”

TNI Module 4 Section 1.7.1.1.g

“the highest calibration standard shall be at or above the highest concentration for which quantitative data are to be reported. Any data reported above the calibration range shall be considered to have an increased quantitative uncertainty and shall be reported using defined qualifiers or explained in the narrative’

TNI Module 2, Section 5.10.11.d (reporting requirements)

“Clear identification of numerical results with values outside the calibration range.”

Glen did not know why the HASQARD gap requirement was retained in the gap checklist. Focus Group members present speculated that it was because the statement about reporting data associated with sample results outside a calibration range using defined qualifiers was not found in the same place as the instructions for diluting and reanalyzing the sample.

Glen stated that unless he hears a reason to not make the suggestion, he will suggest to the DQW that the HASQARD gap checklist requirement be removed.

Hearing no additional new business, Jonathan Sanwald adjourned the meeting at 3:38 PM.

The next meeting of the HASQARD Focus Group will be at 2:00 PM on December 4, 2018 in Conference Room 308 at 2420 Stevens Center Place.